

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	James B. Zagel	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	02 C 4782	DATE	3/23/2004
CASE TITLE	CYTOMEDIX, INC. vs. LITTLE ROCK FOOT CLINIC, ET AL		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

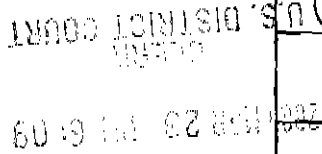
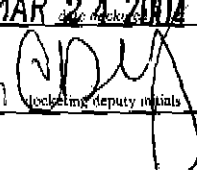
MOTION:

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DOCKET ENTRY:

- (1) ☐ Filed motion of [use listing in "Motion" box above.]
- (2) ☐ Brief in support of motion due ____.
- (3) ☐ Answer brief to motion due _____. Reply to answer brief due _____.
- (4) ☐ Ruling/Hearing on ____ set for ____ at _____.
- (5) ☐ Status hearing[held/continued to] [set for/re-set for] on ____ set for ____ at _____.
- (6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on ____ set for ____ at _____.
- (7) ☐ Trial[set for/re-set for] on ____ at _____.
- (8) ☐ [Bench/Jury trial] [Hearing] held/continued to ____ at _____.
- (9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).
- (10) ☒ [Other docket entry] **Enter memorandum opinion and order regarding claim construction.**

- (11) ☒ [For further detail see order attached to the original minute order.]

<input type="checkbox"/> No notices required, advised in open court.	<div style="text-align: center;">  </div>	number of notices	<div style="text-align: center;"> Document Number 48 </div>
<input type="checkbox"/> No notices required.			
<input type="checkbox"/> Notices mailed by judge's staff.			
<input type="checkbox"/> Notified counsel by telephone.			
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		mailing deputy initials	

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CYTOMEDIX, INC.,

Plaintiff,

v.

LITTLE ROCK FOOT CLINIC, P.A.,
MARVIN F. COHEN, R. ALEX
DELLINGER, and CALVIN P. BRITTON
III,

Defendants.

5:02 C 4782
MAR 23 2014

No. 02 C 4782
Judge James B. Zagel

MEMORANDUM OPINION AND ORDER

Plaintiff Cytomedix, Inc. and Defendants Little Rock Foot Clinic, P.A., Marvin F. Cohen, R. Alex Dellinger, and Calvin P. Britton III have filed memoranda setting forth their respective views on the proper construction of the disputed claims of U.S. Patent No. 5,165,938 ("the '938 patent"). The patent, entitled "Wound Healing Agents Derived From Platelets," was filed on November 29, 1984, and issued on November 24, 1992. The Regents of the University of Minnesota and Curative Technologies, Inc. filed the patent application on behalf of named inventor, David R. Knighton. Ownership was later transferred to Cytomedix.

Law Regarding Claim Construction

The object of claim construction is to determine what sometimes terse or unfamiliar words in patent claims mean. *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The primary sources to be consulted when construing a patent claim are: (1) the

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language of the claim, (2) the patent's specification, and (3) the prosecution history of the patent. *Gart*, 254 F.3d at 1340; *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996); *Markman*, 52 F.3d at 979-80. These sources are called the "intrinsic evidence," as they are public record available for all to consult when determining the meaning and scope of a patent claim.¹

Claim interpretation begins with the actual words of the claims. *Bell Communications Research v. Vitalink Communications Corp.*, 55 F.3d 615, 619-20 (Fed. Cir. 1995). Generally, the words, phrases, and terms in patent claims should receive their ordinary and accustomed meaning. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). Hence, I should not rewrite the claims either by disregarding words that are present or adding others that are not. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 (Fed. Cir. 1987). Furthermore, words not present in the claims cannot suddenly become claim limitations. *International Visual Corp. v. Crown Metal Mfg. Co.*, 991 F.2d 768, 771-72 (Fed. Cir. 1993). Indeed, the strong presumption in favor of the ordinary meaning may only be overcome when the patentee clearly sets forth a definition for claim term in the patent specification. *Anchor Wall Sys. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1306 (Fed. Cir. 2003) (citing *Johnson Worldwide*, 175 F.3d at 989-90). Finally, in determining the ordinary meaning of claim terms, I may freely consult dictionaries, encyclopedias, or treatises that were publicly available at the time

¹ When the intrinsic evidence unambiguously describes the scope of a patented invention, reliance on "extrinsic evidence," such as expert testimony and treatises, is improper. *Vitronics*, 90 F.3d at 1583; *Digital Biometrics v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998). In this case, neither party claims that extrinsic evidence is needed in the claim construction.

the patent was issued, as objective and reliable sources of the established meanings that would have been attributed at the time to the terms of the claims by those of skill in the art. *Texas Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1202-03 (Fed. Cir. 2002). In fact, these resources are often considered the most meaningful in determining the ordinary meaning of claim terms. *Id.* at 1203.

The patent specification is the first resource beyond the actual words of the claims themselves to aid in claim construction. *Fromson v. Anitec Printing Plates*, 132 F.3d 1437, 1442 (Fed. Cir. 1997). In general, technical terms are deemed to have the same meaning in the claims as in the body of the specification. *Id.* I may additionally review the specification as an aid in determining the meaning of a claim term in the context of the entirety of the disclosed invention. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 231 F.3d 859, 866 (Fed. Cir. 2000). In looking to the specification, however, the claims are not limited to the embodiment(s) shown in the specification. *Anchor Wall Sys.*, 340 F.3d at 1307; *Transmatic, Inc. v. Gulton Indus.*, 53 F.3d 1270, 1277 (Fed. Cir. 1995). Similarly, other limitations appearing only in the specification cannot be read into a claim because “the claim, not the specification, measures the invention.” *Howes v. Zircon Corp.*, 992 F.Supp. 957, 961 (N.D. Ill. 1998) (citing *SRI Int’l v. Matsushita Elec. Corp.*, 775 F.2d 1107 (Fed. Cir. 1985)).

Each patent has a corresponding publicly available record called the prosecution history that details the proceedings before the Patent and Trademark Office (“PTO”). The prosecution history may limit the interpretation of claim terms to exclude any interpretation that was disclaimed during prosecution to overcome or distinguish the prior art. *Vitronics*, 90 F.3d at 1583. However, “unless altering claim language to escape an examiner rejection, a patent

applicant only limits claims during prosecution by clearly disavowing claim coverage.”

Kopykake Enters. v. Lucks Co., 264 F.3d 1377, 1382 (Fed. Cir. 2001) (quotation omitted). Any such disavowal, or surrender, “must be clear and unmistakable.” *Anchor Wall*, 340 F.3d at 1307.

Claim Terms Requiring Construction

The terms whose meanings are in dispute appear in independent claims 1 and 12 of the ‘938 patent. Those claims are set forth below with the terms in dispute emphasized:

1. A process for treating damaged, live, animal tissue which comprises applying over the damaged tissues an ***effective amount*** of a ***treating composition containing the materials released by platelets during the platelet release reaction*** and facilitating healing of the damaged tissue.
12. A process for treating a wound of a live animal which comprises applying over the wound an ***effective amount*** of a ***treating composition containing the materials released by platelets during the platelet release reaction*** and facilitating healing of the wound.

“Effective Amount”

The term “effective amount” should be construed to mean “a sufficient amount of treating composition to facilitate healing.” First, the language of the claim supports this conclusion. It is a common and accepted practice to claim an invention in terms of an “effective amount” of an ingredient or substance where the amount is not critical and those skilled in the art could determine specific values for the amount based on the patent disclosure. See *Manual of Patent Examining Procedure* § 2173.05[c]; *In re Mattison*, 509 F.2d 563, 565 (C.C.P.A. 1975); *In re Halleck*, 422 F.2d 911, 914 (C.C.P.A. 1970). The ordinary meaning of “effective” is “producing a . . . desired effect.” *Webster’s Ninth New Collegiate Dictionary* 397 (1990). The Federal

Circuit has expressly recognized that the term “effective amount” has a customary usage of a sufficient amount to provide the claimed result. *See 3M v. Chemque, Inc.*, 303 F.3d 1294, 1299, 1304 (Fed. Cir. 2002), *cert. den.*, 123 S. Ct. 1779 (2003) (affirming construction of “effective amount” to mean “a sufficient amount of the specified component to form [claimed] encapsulant having the specified properties under the specified conditions, if any”); *see also Abbott Labs. v. Baxter Pharm. Prods.*, 334 F.3d 1274, 1277-78 (Fed. Cir. 2003) (customary meaning required construing “effective amount” to mean the amount of claim Lewis acid inhibitor needed to provide claimed result of preventing degradation of sevoflurane).

The patent specification also supports the conclusion that “effective amount” refers to “a sufficient amount of treating composition to facilitate healing.” One skilled in the art would understand from the specification that an effective amount of a treating composition will vary depending on many considerations. The specification describes the complex process of tissue healing, and explains the many platelet derived factors involved in the healing process. It discloses that the treatment compositions of the invention are effective for many different types of wounds, including external wounds and internal wounds. The specification also suggests that the treating compositions of the invention may be placed over the entire wound at a relative uniform thickness. Alternatively, sutures may be impregnated with the composition to speed internal healing, or the compositions may be coated over implantable devices or surgical instruments. Disclosed examples of wounds successfully treated according to the invention include an open foot wound, a large amputation stump, and nonhealing ulcers in diabetic patients. In each case, the treatment therapy occurred over extended periods of time. The specification does not suggest that the amount of treating composition used is critical. Rather it

is apparent from the disclosed wide-ranging applicability of the invention that the effective amount of treating composition will depend on the nature and severity of the particular wound, the application method, the patient's overall health, the desired rate of healing, and other factors assessed by the treating professional. Moreover, the disclosed methods for preparing the treating compositions of the invention involve isolating platelets from blood. The blood may be taken from the injured animal or from another animal of the same species. The resulting platelet-rich plasma may be further concentrated, diluted in a buffer, and/or mixed with a carrier to form a paste. Several different activators may be used to release the various healing factors from the platelets. Thus, the '938 patent teaches that the make-up of treating compositions made according to the invention may vary considerably. Persons in the art would also understand that the specific formulation of the composition may impact the preferred amount to be applied. This provides additional evidence that the patentee did not deviate from the accustomed meaning of "effective amount" by requiring that a particular amount of treating composition be applied during the treatment protocol.

Finally, the prosecution history also supports the conclusion that "effective amount" refers to an amount sufficient to facilitate healing. Application claims 20-65 were pending at one stage of the prosecution. Those claims included several method claims directed to applying a treating composition "in an amount sufficient to cause" certain claimed results relating to tissue healing. The PTO Examiner rejected these claims over the prior art and also under 35 U.S.C. § 112 as non-enabled "since the dosage of active ingredients to be used in the treatment is not set forth." Claims 20-65 were then cancelled and replaced by claims 66-90. Several of the

substituted claims also used the "amount sufficient to cause" terminology. The patentee responded to the Examiner's previous objection to that phrase under § 112 as follows:

Applicant's invention includes the broad concept, for example, that compositions containing substances which are chemotactic for capillary endothelial cells, particularly the materials released from platelets, can be applied topically to induce the formation of capillaries for cosmetics and wound healing. This concept encompasses all dosages of such compositions that will produce the result that applicant has discovered is achievable by such means. Therefore, the specific dosage of such compositions is not critical to the invention as defined by [the] claims . . . From the disclosure, including the examples, those in the art will be able to determine, without undue experimentation, what dosage of such compositions is necessary to achieve the result recited by the claims.

This response also drew the Examiner's attention to the case *In re Halleck*, which condoned use of the phrase "effective amount" in a growth stimulating composition for animals. 422 F.2d 911. The response equated the phrase to the phrase "amount sufficient to cause" present in the then-pending claims in asserting that those claims were also properly enabled without reciting a specific dosage. The Examiner thereafter withdrew the non-enablement rejection premised on the phrase "amount sufficient to cause." That phrase was eventually replaced by the term "effective amount" in the issued claims. Thus, the prosecution history confirms that the term "effective amount" was used in its ordinary sense to mean a sufficient amount to achieve the claimed result of facilitating healing.

Defendants argue that the term "effective amount" should be construed to mean "8-10 ml of supernatant per gram of carrier." As an initial matter, Defendants' proposed construction would have the phrase specify the make-up of the treating composition and the relative proportions of its components, which is not an "amount." Construing "effective amount" as such would also arguably add new limitations which are not present in the claims, a practice

prohibited in claim construction. *See, e.g., Storage Tech. Corp. v. Cisco Sys.*, 329 F.3d 823, 831 (Fed. Cir. 2003); *International Visual Corp.*, 991 F.2d at 771-72.

However, Defendants' main argument for construing the term "effective amount" as "8-10 ml of supernatant per gram of carrier" is the prosecution history, namely that the application expressly defined the phrase "an effective amount" by making reference to a portion of the specification during prosecution. But even if the applicant had made reference to the specification for purpose of defining the phrase "an effective amount," the passage referenced does not support Defendants' argument. It reads:

The resultant composition is thicker and will tend to remain in position in contact with the wound. Debrisan brand wound dressing which contains Sepharosc brand beads, trademarks of Pharmacia Fine Chemicals, Inc. of Piscataway, New Jersey, may be utilized as an alternative carrier. Preferably, about 8-10 ml of supernatant per gram of carrier is used to produce a paste. Application of the wound treating composition is by physically applying the material over an [sic] into the wound as in applying a medicated salve. Treatments should be repeated on a daily basis as long as the wound remains open. A preferred treatment is to apply an approximately one mm thick dressing of the platelet factor/carrier complex to the wound in the morning.

Most apparent is that the disclosure of using a paste containing about 8-10 ml of supernatant per gram of carrier is only a *preferred* composition of the paste, not the amount of its application. *See Transmatic*, 53 F.3d at 1277 ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."). There is nothing indicating that this particular preferred paste composition is required by the claims. Moreover, the portion of the passage more pertinent to the claim phrase "an effective amount" of the treating composition is the disclosure of applying "an approximately one mm thick dressing" of the composition to the wound in the morning. But this too is expressly described as a "preferred treatment," not a required treatment.

“Treating Composition Containing the Materials Released by Platelets During the Platelet Release Reaction”

The term “treating composition containing the materials released by platelets during the platelet release reaction” should be construed to mean “a composition that has all of the various components released by platelets during the platelet release reaction and may have other components.” First, the language of the claim supports this conclusion. The ordinary meaning of the term “composition” is “a product of mixing or combining various elements or ingredients.” *Webster’s Ninth New Collegiate Dictionary* 270 (1990). Courts have recognized that the ordinary meaning of “composition” is open-ended and includes mixtures having the recited ingredients and other substances. See e.g., *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316, 334-35 (D. Del. 2001). The term “contain” means “to have within . . . comprise, include.” *Webster’s Ninth New Collegiate Dictionary* 282 (1990). The term “include” means to contain within as part of a whole” and “suggests the containment of something as a constituent, component, or subordinate part of a larger whole.” *Webster’s Ninth New Collegiate Dictionary* 609 (1990). Thus, the ordinary meaning of a “treating composition containing the materials released by platelets” encompasses compositions containing substances in addition to the materials released by platelets. The phrase does not recite a composition containing only those materials, and claims should not be rewritten to add words not present. *Panduit*, 810 F.2d at 1576.

The patent specification supports the conclusion that the term should be construed as “a composition that has all of the various components released by platelets during the platelet release reaction and may have other components.” The specification does not demonstrate that

the patentee deviated from the customary, open-ended nature of the phrase "composition containing." In the "Summary of the Invention" section, the patent emphasizes the discovery that activated platelet-enriched plasma ("PRP") contains platelet-derived angiogenesis factor ("PDAF") and growth factor ("PDGF") which may be used to speed the healing of wounds. The specification refers repeatedly to applying "activated PRP" to wounds as a healing agent, without mention of removal of platelet ghosts (the residual platelet body that remains after a platelet releases all of its alpha-granule contents during the platelet release reaction) from the activated PRP. Also, the specification of the '938 patent includes the nineteen originally filed application claims directed to treating compositions and methods for their preparation and use. Only one of those original claims requiring isolating PDAF and PDGF from activated PRP, which further demonstrates that the disclosed invention is not limited to using platelet derived factors isolated from platelet ghosts. Because specification simply does not indicate that the patentee restricted its claims to any preferred embodiment, the treating compositions of the claims are not limited to compositions free of platelet ghosts or other non-related materials.

Finally, the prosecution history supports the construction that the treating composition can have all of the various materials released by activated platelets. The PTO rejected application claims on the basis of prior art references disclosing that isolated PDGF may be beneficial in wound healing. In a Response dated November 18, 1989, the term "material released from platelets" was distinguished from isolated growth factor as follows:

This phrase refers to the actual physical stuff or soup in its entirety which is released by platelets -- without further processing or isolation of factors contained therein. This material is very complex, admittedly containing PDGF but also containing platelet-derived angiogenesis factor and many other growth factors and inhibitors including fibroblast growth factor ("FGF"), epidermal growth factor ("EGF"), TGF-d, TGF-B, platelet factor 4, and many others.

After the PTO Examiner maintained the position that "material released by platelets" was broad enough to cover isolated PDGF, the pending claims were amended to replace that phrase with the expression "the materials released by platelets during the platelet release reaction." The patentee emphasized that the substituted expression refers to "all of the various components" released and not just "*one or more* of the materials released." (emphasis in original) The patentee consistently applied this meaning to the term in distinguishing the issued claims from the prior art. The Examiner eventually recognized this distinction, and indicated in the Notice of Allowability that "the materials released by platelets during the platelet release reaction" referred to "materials more complex than PDGF." Because the patentee expressly defined the term "the materials released by platelets during the platelet release reaction" during prosecution to require all of the various components released, the claimed treating composition must include all of the various released components. *Honeywell Inc. v. Victor Co. of Japan, Ltd.*, 298 F.3d 1317, 1323-24 (Fed. Cir. 2002) (definition of term offered during prosecution relevant to intended meaning of term).

Defendants argue that the term "treating composition" should be construed as the union of a "biologically compatible macromolecular substance" to the "platelet-free supernatant," *i.e.*, "the materials released by platelets," and that "containing the materials released by platelets during the platelet release reaction" should be construed to mean "platelet-free supernatant." However, limiting the phrases as such would contradict the ordinary meanings of the terms "composition" and "containing," namely that both terms are by nature open-ended and permit inclusion of other components. The patent claims nowhere indicate that platelet ghosts or other non-related substances must be removed to make the compositions of the invention effective healing agents.

Defendants' proposed construction is also not supported by the specification. The specification includes the nineteen originally filed application claims directed to treating compositions and methods for their preparation and use. The majority of those claims described preparation methods and resulting compositions which included platelets as well as released materials. Defendants attempt to suggest that the invention is limited to platelet-free supernatants and a carrier by focusing on parts of the preparation methods described elsewhere in the patent specification. These preparation methods, however, only serve to illustrate preferred ways of making embodiments in accordance with the invention. The law is clear that claims are not limited to a preferred embodiment disclosed in the specification. *Transamatic*, 53 F.3d at 1277. But even if the specification did contain some limitations, limitations appearing only in the specification cannot be read into the claims. *Howes*, 992 F.Supp. at 961.

Finally, the prosecution history does not support the Defendants' construction of this term. Defendants argue that the applicant disavowed the scope of coverage of the claims directed to the use of activated platelet-rich plasma applied to a wound. Contrary to this assertion, however, the applicant never gave up on claims directed to the use of activated platelet-rich plasma applied to a wound, *i.e.*, what Defendants call "one centrifuge cycle" claims.

The original application for the '938 patent contained fifteen claims as filed, which were directed to various treatments and methods of the invention. For example, the initial claims covered methods for producing wound healing substances through platelet activation with thrombin and the use of a carrier, methods for extracting PDAF and PDGF from blood, and platelet-derived compositions for the treatment of wounds. Application claim 13 described a treatment composition comprising PDAF and PDGF in a platelet-rich plasma also containing thrombin. As acknowledged by Defendants, the initial claims included broad claims directed to

the use of the activated platelet-rich plasma applied to a wound; the claims were not limited to a platelet-free supernatant and a carrier.

Following the Examiner's rejection of the claims, the initial application was abandoned in favor of a related application. The new disclosure included additional information summarizing results of clinical trials with diabetic patients. This application presented nineteen claims for consideration, many of which were claims carried over from the original parent application.

Application claims 1-19 were thereafter cancelled and replaced with claims 20-65. Newly presented claims 47-56 were directed to treatment methods involving topical application to tissue of material released from platelets. Thus, as shown by application claims 47-56, the applicant continued to pursue claims directed to the use of activated platelet-rich plasma applied to a wound. Contrary to Defendants' argument, nothing in the prosecution history suggests that claims 47-56 "inherently required two centrifuge cycles." Applicant subsequently cancelled claims 20-65 and replaced them with application claims 66-90. Claims 76-86 recited a method for treatment of tissue "comprising applying materials released from platelets topically onto tissue." There was no requirement of a carrier or of a platelet-free supernatant. Thus, in pursuing claims 76-86, the applicant did not limit itself to a platelet-free supernatant and a carrier, *i.e.*, what Defendants call a "three centrifuge cycle."

In a series of communications with the PTO addressing claims 76-89 and successor claims, the applicant clarified the meaning of the phrase "materials released by platelets," which was later replaced by the phrase "the materials released by platelets during the platelet release reaction." The applicant explained that this phrase was directed to methods and treatments containing all of the materials released by platelets during the platelet release reaction after activation and not to any one isolated component of these materials. These exchanges between

the applicant and the Examiner show that both the applicant and Examiner understood the phrase to have this meaning.

Furthermore, the Examiner's statements from the Notice of Allowability show that the Examiner allowed the claims based on this clarification of "materials released by platelets during the platelet release reaction." The Examiner allowed the claims because the prior art did not show the use of all the materials released by activated platelets, which "are materials more complex than PDGF" alone. The Examiner therefore allowed the claims because applicant was not seeking claim coverage of any one released factor, such as PDGF, alone. The Examiner's understanding of the claims, as stated in his reasons for allowance, should be considered in construing the claims. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (7th Cir. 1999).

Significantly, the applicant made no effort to distinguish the prior art by limiting the claims to a platelet-free supernatant and a carrier. In addition, there is no indication in the prosecution history that the Examiner required such an implicit limitation as a condition for allowance. The applicant cannot be said to somehow have incorporated the requirements of a platelet-free supernatant and a carrier.

Defendants argue that the applicant narrowed the definition of the claimed treating composition to include only the "supernatant" remaining after a "third centrifugation cycle." They quote a passage from an amendment to support their argument that the applicant expressly limited its treatment method to compositions containing the supernatant and not compositions containing the supernatant plus additional materials. This argument, however, is not supported by the very amendment they quote. First, the passage from the specification describing preparation of a platelet-free supernatant was referred to by the applicant only to show that the claims were adequately supported by the specification, and not to define the phrase now at issue.

Moreover, the full text of the applicant's remarks shows that the applicant was emphasizing an intent to claim "all of the various components" of the materials released during the platelet release reaction, not just "one or more of the materials released." To further emphasize this point and to show that the claim was adequately supported, the applicant referred to a preferred embodiment in the specification describing the preparation of a platelet-free supernatant:

P. 5, lines 15-34 [of the specification] set forth the procedure for preparing the materials released by platelets. After the release reaction the platelet ghosts and fibrin are removed by centrifugation (see p. 5, lines 24-26). The resultant "supernatant" is what is applied to a wound in toto (see p. 5, lines 33-35). *Applicant does not isolate individual factors from this supernatant and does not otherwise process this supernatant in ways that would affect the bioactivity of the multitude of factors contained therein.* Applicant "names" this supernatant "the materials released by platelets in the platelet release reaction" . . . This phrase refers to the actual physical stuff or soup in its entirety which is released by platelets – without further processing or isolation of factors contained therein.

(emphasis in original). Viewed in the proper context, this passage emphasized: (1) that the claim was adequately supported by a preferred embodiment of the specification in which the materials released by platelets were in the form of a platelet-free supernatant; (2) that the disclosed supernatant was not further separated into isolated factors; and (3) that the specification therefore supported a definition of the materials released by platelets as all of the various components released. The concluding sentence of the applicant's remarks reiterated the salient point that the "material released from platelets" refers to the "actual physical stuff or soup in its entirety which is released by platelets – without further processing or isolation of factors contained therein." A person of ordinary skill would not conclude from this exchange that the claims were limited to compositions free of platelet ghosts.

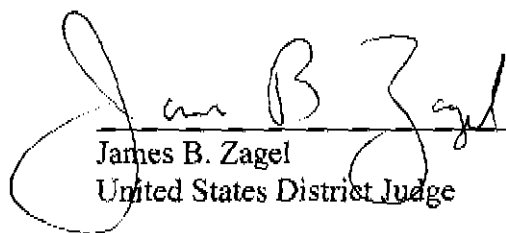
Furthermore, the prosecution history in its entirety shows just the opposite of what Defendants contend. At one point during prosecution the patentee introduced independent claims 76 and 87. Claim 76 was directed to a method for treatment of tissue "comprising

applying material released from platelets topically onto tissue." Independent claim 87 more narrowly recited a composition comprising a carrier and the material released from platelets, and also required that the composition be "substantially free of (i) blood or plasma contaminants and (ii) platelet ghosts or other material found in human platelets but not released by said platelets." Application claim 89 recited a treatment method comprising topically applying the composition of claim 87 onto the tissue. Application claims 76 and 87-89 were later cancelled and replaced with claims similar to the broader claim 76, which later issued as claims 1 and 12. Thus, the narrower claim scope of claims 87-89 was abandoned in favor of the broader issued claims 1-12, which does not require the absence of non-released materials in the treating composition.

Conclusion

The term "effective amount" as used in claims 1 and 12 of the '938 patent means "a sufficient amount of treating composition to facilitate healing." The term "treating composition containing the materials released by platelets during the platelet release reaction" as used in claims 1 and 12 of the '938 patent means "a composition that has all of the various components released by platelets during the platelet release reaction and may have other components." Enter opinion and order construing disputed claim terms.

ENTER:


James B. Zagel
United States District Judge

DATE: 23 March 2004